K132216

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510(k) Summary

SEP 09 2013

Submitter Information:

Date Prepared:	July 16, 2013
Name:	Bausch & Lomb Incorporated
Address:	1400 North Goodman Street Rochester, NY 14609
Contact Person:	Heather Michaels Senior Specialist, Global Regulatory Affairs
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Device Information:

Trade Name:	Bausch + Lomb PeroxiClear™ 3% Hydrogen Peroxide Cleaning & Disinfecting Solution
Common Name:	Contact Lens Disinfection Solution
Device Classification:	Class II
Classification Name:	Soft (hydrophilic) Contact Lens Care Products (21 CFR 886.5928) Rigid Gas Permeable Contact Lens Care Products (21 CFR 886.5918)
Product Codes:	LPN, MRC

Predicate Device:

The predicate device is Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution (K112909).

Device Description:

Bausch + Lomb PeroxiClear™ 3% Hydrogen Peroxide Cleaning & Disinfecting Solution (referred to as PeroxiClear) is a sterile, buffered solution containing 3% hydrogen peroxide (which contains a phosphonic acid stabilizer), potassium chloride, propylene glycol, carbamide (urea), a citrate/phosphate buffer system, and a poloxamer (P-181) surfactant. The sterile solution is aseptically filled and packaged in ethylene oxide (EtO) sterilized plastic bottles with a tamper-evident seal and labeled with a lot number and expiration date. A special lens case, containing a platinum-coated neutralizing disc, is provided with each bottle of PeroxiClear. This is the same lens case as provided with the previously cleared device.

The solution and lens case combined are considered a lens care system. As with the previously cleared device, the solution requires the use of the provided lens case specifically designed for neutralization of the peroxide and cannot be used in combination with any other lens case. The system is designed to clean and disinfect contact lenses by filling solution into the provided lens case and allowing the lenses to soak for a minimum of four hours. During the soaking period, the hydrogen peroxide is neutralized by a platinum-coated disc, thereby allowing the lenses to be safely inserted in the eye.

Intended Use:

Bausch + Lomb PeroxiClear™ 3% Hydrogen Peroxide Cleaning & Disinfecting Solution is intended for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

The intended use above is identical to what was cleared in the original 510(k) (K112909).

Technological Characteristics:

The table below shows a side-by-side comparison of the technological characteristics of the modified device to the previously cleared device. Differences were evaluated during the design and development of the modified device and testing was completed to demonstrate the modified device and predicate device are substantially equivalent and the differences do not negatively impact the safety and efficacy of the device.

Table 1. Comparison of Technological Characteristics

Feature	**Bausch + Lomb OCD04 3% Hydrogen Peroxide Cleaning and Disinfecting Solution (predicate device)**	**Bausch + Lomb PeroxiClear™ 3% Hydrogen Peroxide Cleaning & Disinfecting Solution (modified device)**
510(k) Number	K112909	K132216
Device Class	Class II	Identical
Regulation	• Soft (hydrophilic) Contact Lens Care Products (21 CFR 886.5928) • Rigid Gas Permeable Contact Lens Care Products (21 CFR 886.5918)	Identical
Product Codes	LPN, MRC	Identical
Indications for Use	Indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.	Identical
Rub Regimen	Yes, only for Rigid Gas Permeable Lenses	Identical
No-Rub Regimen	5 second rinse	Identical
Platinum-Coated Neutralization Disc	Yes	Yes
Lens Case	Designed for System	Identical
Minimum Disinfection Time	4 hours	Identical
Post Disinfection Saline Rinse Prior to Wear	Optional	Identical
Hydrogen Peroxide Content	3%	Identical
Buffer System	Phosphate / Citrate Buffers	Identical
Stabilizer	Phosphonic Acid	Identical
Lens Storage Period	7 days	Identical
Discard After Opening	90 days or 35 uses	Identical
Primary Container (Material and Size)	HDPE Plastic (120 mL, 360 mL)	Identical

Summary of Non-Clinical Testing:

In addition to stability studies, a series of studies were conducted according to EN ISO 14729:2001/AMD.1:2010(E) Ophthalmic optics – Contact lens care products – Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses and EN ISO 14730:2000(E) Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date.

Substantial Equivalence Conclusion:

The results of the non-clinical and stability testing demonstrate that the safety and effectiveness of Bausch + Lomb PeroxiClear™ 3% Hydrogen Peroxide Cleaning & Disinfecting Solution is substantially equivalent to the previously cleared device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

September 9, 2013

Bausch & Lomb Incorporated
Ms. Heather Michaels
Senior Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Re: K132216
Trade/Device Name: Bausch + Lomb PeroxiClear™ 3% Hydrogen Peroxide Cleaning & Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: August 16, 2013
Received: August 19, 2013

Dear Ms. Michaels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132216

Device Name:

Bausch + Lomb PeroxiClear™ 3% Hydrogen Peroxide Cleaning & Disinfecting Solution

Indications for Use:

Bausch + Lomb PeroxiClear™ 3% Hydrogen Peroxide Cleaning and Disinfecting Solution is indicated for the daily cleaning, removal of protein deposits, disinfection, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel) and rigid gas permeable contact lenses, as recommended by your eye care practitioner.

Prescription Use_____ AND/OR Over-The-Counter Use__X__
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Leonid Livshitz -S
2013.09.06 '00'04- 10:25:37

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number: K132216